

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 05-586 (KAJ)
	)	(Consolidated with
ANDRX PHARMACEUTICALS, LLC and	)	C.A. No. 06-620)
ANDRX CORPORATION,	)	
	)	
Defendants.	)	

**BIOVAIL’S RULE 30(b)(6) NOTICE TO ANDRX**

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiff Biovail Laboratories International SRL (“Biovail”), by its attorneys, will take the deposition upon oral examination of Defendants Andrx Pharmaceuticals, LLC and Andrx Corporation (collectively “Andrx”), which shall designate one or more officers, directors or other persons who consent to testify on its behalf about matters set forth in the attached Schedule A, including information in the possession, custody and control of Andrx.

The deposition will commence at 9:30 a.m. on December 13, 2006, at the offices of Fitzpatrick, Cella, Harper & Scinto, 30 Rockefeller Plaza, New York, New York 10112, or at such other time and place as counsel may mutually agree upon, and will continue from day-to-day, weekends and legal holidays excluded, until completed. The deposition will be conducted before a notary public or other officer duly authorized by law to administer oaths and will be recorded by a certified shorthand reporter and by videotape. Separately for each numbered category in Schedule A, Andrx shall identify to Biovail no later than 7 days before the date of the deposition, the person(s) designated to testify on Andrx’s behalf.

You are invited to attend and cross-examine.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs Louden*

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# EXHIBIT A

## **SCHEDULE A**

### **Definitions**

1. The term “thing” means any physical specimen or other tangible item other than a document.

2. The term “document” is used in the broadest sense possible under Rule 34 of the Federal Rules of Civil Procedure, and means any writing or other record whatsoever of every nature, whether transcribed by hand or by some mechanical, electronic, photographic or other means, and regardless of the medium in, or upon which, it is retained or stored, including, without limitation, the following: correspondence; memoranda; electronic mail; notes; records; summaries of meetings or conferences; opinions; studies; reports of consultants; projections; statistical statements; drafts; contracts; agreements; telegrams; telexes; facsimiles; books; pamphlets; manuals; reports; diaries; tape recordings; computer discs; tapes or files; charts; logs; photographs; notebooks; drawings; plans; rules; rulings; regulations; orders; codes; and inter-office communications. “Document” includes every copy of a document that is not identical to the original or any other copy.

3. The term “plaintiff” as used hereinafter includes Biovail Laboratories International SRL, its past or present officers, directors, employees, representatives, agents and attorneys, as well as any past or present predecessor, successor, parent, subsidiary, division or affiliate thereof, whether domestic or foreign, whether owned in whole or in part.

4. The term “defendant” as used hereinafter includes Andrx Pharmaceuticals, LLC, and Andrx Corporation, its past or present officers, directors, employees, representatives, agents and attorneys, as well as any past or present predecessor, successor, parent, subsidiary, division or affiliate thereof, whether domestic or foreign, whether owned in whole or in part.

5. The term “the ’866 patent” means United States Patent No. 7,108,866 entitled “Chronotherapeutic Diltiazem Formulations and the Administration Thereof”.

6. The term “diltiazem hydrochloride compositions” means any drug product(s) that includes diltiazem hydrochloride as its active ingredient, regardless of the name or designation used in a particular document or thing.

7. The term “defendant’s diltiazem hydrochloride composition(s)” means the drug products, including but not limited to, the active ingredient and all other components (including excipients) which comprise each strength of each drug product which is the subject of Abbreviated New Drug Application No. 77-686, and any other diltiazem hydrochloride product which defendant has tested, evaluated, purchased, or otherwise acquired or sold.

8. The term “FDA” means the United States Food and Drug Administration.

9. The term “NDA” means New Drug Application.

10. The term “ANDA” means Abbreviated New Drug Application.

11. The term “plaintiff’s NDA” means NDA No. 21-392.

12. The term “defendant’s ANDA” means ANDA No. 77-686, including any updates, supplements, amendments, revisions, etc.

13. The term “prior art” encompasses, by way of example and without limitation, the subject matter described in each and every subdivision of 35 U.S.C. § 102 and 35 U.S.C. § 103.

14. The term “excipient” means, for the basis of these requests only, any substance other than the active ingredient in a drug composition.

15. The term “calcium channel blocker” or “CCB” means any composition that blocks the entry of calcium into a cell.

16. The singular form of any noun or pronoun used herein includes within its meaning the plural form thereof and vice versa; the neuter, masculine or feminine form of any pronoun used herein includes within its meaning the neuter, masculine and feminine forms; and the use herein of any tense of any verb includes within its meaning all other tenses of the verb. In every such instance, the specific request shall be construed in the broadest sense so as to call for the most complete and inclusive answer.

17. The term “relating to or concerning” means referring to, describing, evidencing or constituting.

18. The conjunctions “and” and “or” shall be individually interpreted in every instance as meaning “and/or” and shall not be interpreted disjunctively to exclude any document or thing otherwise within the scope of any request.

### **SUBJECTS OF EXAMINATION**

1. Andrx's first awareness of Biovail's '866 patent, any application that led to the issuance of the '866 patent, or any foreign counterpart, as well as Andrx's analysis, consideration or review of the '866 patent, or any foreign counterpart, and how it might affect Andrx's activities relating to ANDA No. 77-686 of defendant's generic diltiazem hydrochloride compositions.

2. Andrx's consideration, evaluation or analysis of the validity of the '866 patent, including the identity of any person(s) involved in the consideration, evaluation or analysis of the '866 patent; the date(s) of any such consideration, evaluation or analysis; and the identity of all documents constituting, forming the basis of, or relied on in making, any such consideration, evaluation or analysis.

3. The facts that formed the basis for the statement in Andrx's September 19, 2006 Paragraph IV certification notice letter to Biovail that "[w]ith respect to United States Patent No. 7,108,866 (the '866 patent), the Andrx Proposed Product does not infringe any valid and enforceable claim...."

4. The timing, determination and information used by Andrx to consider whether to file a Paragraph IV patent certification and notice letter, with respect to the '866 patent including:

- a. The date when, and the circumstances under which, Andrx sought any legal opinion concerning the infringement, validity or unenforceability of the '866 patent.
- b. The information provided by or for Andrx to any lawyer or other person in connection with any opinion sought or obtained by Andrx

concerning the infringement, validity or unenforceability of the '866 patent.

- c. The information provided by or for any lawyer or other person to Andrx in connection with any opinion sought or obtained by Andrx concerning the infringement, validity or enforceability of the '866 patent.
- d. All communications between any lawyer and Andrx relating to any opinion sought or obtained by Andrx concerning the infringement, validity or enforceability of the '866 patent.
- e. Whether Andrx intends to rely on any written or oral legal opinions it has received or is in the process of receiving.
- f. Any other written or oral opinions sought or obtained by Andrx relating to the infringement, validity or enforceability of the '866 patent.
- g. The preparation of, research involving and decision to send Andrx's notice letter and patent certification to Biovail regarding the '866 patent.

5. Bioavailability, bioequivalence, and pharmacokinetics studies or trials of defendant's diltiazem hydrochloride compositions, including but not limited to:

- a. The data, analysis and results of all pharmacokinetic studies or trials regarding defendant's diltiazem hydrochloride compositions;
- b. All proposed and actual protocols used to conduct such pharmacokinetic studies or clinical trials;



- c. Bioavailability of defendant's diltiazem hydrochloride compositions at night compared to when given in the morning without food;
- d. Bioequivalence of defendant's diltiazem hydrochloride compositions when given in the morning with or without food; and
- e. For defendant's diltiazem hydrochloride compositions all data concerning Cmax, including but not limited to methods and protocols for determining Cmax.

6. Bioavailability, bioequivalence, or pharmacokinetic studies or trials comparing defendant's diltiazem hydrochloride compositions with Cardizem LA, including data, results and analysis of those studies or trials.

7. All communications between PRACS Institute and Andrx regarding any bioavailability, bioequivalence, and pharmacokinetics studies or clinical trials relating to defendant's diltiazem hydrochloride compositions, including results, testing, data or analysis of those studies or trials.

8. All dissolution testing performed by Andrx or on its behalf relating to defendant's diltiazem hydrochloride compositions or pellets used in its proposed products, including all dissolution data, and analysis of same, for all lots or batches of Andrx's proposed generic Cardizem LA products or pellets used in those products, including but not limited to dissolution testing using an aqueous medium and/or medium buffered having a pH from about 5.5 to about 6.5.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on October 17, 2006, I caused to be electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Richard L. Horwitz  
Potter Anderson & Corroon LLP

and that I caused copies to be served upon the following in the manner indicated:

**BY HAND**

Richard L. Horwitz  
Potter Anderson & Corroon LLP  
Hercules Plaza, 6th Floor  
1313 North Market Street  
Wilmington, DE 19899

**BY FEDERAL EXPRESS**

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*/s/ Karen Jacobs Loudon*

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